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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Darin G. Schaeffer

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

08/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/608,043	Applicant(s) SCHAEFFER ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-38, 40 and 46-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-38, 40, and 46-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 46 is objected to because of an informality, which can be corrected as follows: In line 8, after "sheath," insert –body--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 29-35, 37, 38, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyd (3,831,587). Boyd discloses, at least in figures 1-4 and in col. 3, line 7 to col. 4 line 32; an introducer sheath including a sheath body (26) configured to have an axial opening therethrough, the sheath body selectively movable between a non-expanded condition and a radially expanded condition, the sheath body including a proximal portion and a distal portion including a folded portion when the sheath body is in the non-expanded condition (e.g., see fig. 1) and an extended portion when the sheath body is in the radially expanded condition (e.g., see fig. 2 or 3); a hemostatic valve member (24); an insertion member (12) that is a cannula, and a handle (22) including a perimetrical opening (at 24 or 18, where the handle itself has an opening), where the insertion member is receivable within the sheath body axial opening (at 16, where outer portion 32 of the sheath body defines the axial opening receiving the

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insertion member), where the folded distal portion is folded within an inner lumen of the cannula (e.g., see fig. 1), where the introducer sheath includes a pusher member (20), where the handle is generally C-shaped (see element 22 in fig. 1) and comprises a circumferential opening (at 24 or 18, where the handle itself has an opening), where the sheath body comprises a low friction non-rigid material (e.g., nylon or rubber), where the sheath body comprises an axial slit (34) extending substantially along the length of the sheath body (in the non-expanded condition), where the handle includes a ring member (at 18), where the handle comprises a pivotable portion (along 22) and a disengageable portion (at 18), and where the handle is maneuverable into open and closed (i.e., looped) positions.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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5. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd (3,831,587). Boyd discloses the invention substantially as claimed. Boyd discloses an introducer sheath with a sheath body comprising "well known rubber and synthetic materials" (col. 3, lines 57-61), but does not disclose that the sheath body comprises expanded polytetrafluoroethylene. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the sheath body out of expanded polytetrafluoroethylene, since it has been held that to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended uses as a matter of obvious design choice.

6. Claims 46 and 49-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd (3,831,587) in view of Panzer (3,721,229). Boyd discloses the invention substantially as claimed. Boyd discloses an introducer sheath system including an introducer sheath as claimed, the introducer sheath comprising an insertion cannula receivable within an axial opening of a sheath body and handle as claimed, and where the distal end of the sheath body is foldable within an inner lumen of the insertion cannula, where the system includes a pusher mechanism (20), a cap (24), and insertion cannula (12) as an assembly releasable as a unit from the system following radial expansion of the sheath body. However, Boyd does not disclose that the system includes a dilator engaged with the introducer sheath and having a tapered tip extending distal of the sheath body. Panzer teaches, at least in the figures and in col. 4, lines 9-39; a dilator (10) for a body cavity (e.g., a vaginal canal, where Boyd's system may be applied), where the dilator has a tapered tip. It would have been obvious to one

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having ordinary skill in the art at the time the invention was made, in view of Panzer, to include a dilator in the system of Boyd. Such a device would allow a surgeon to access a body cavity (e.g., a cervical canal) through and beyond the introducer sheath for the introduction of therapeutic or radiographic agents into the body cavity.

7. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd (3,831,587) in view of Panzer (3,721,229), and further in view of Gill et al. (5,139,511). Boyd in view of Panzer discloses the invention substantially as claimed, but do not disclose a sheath member for the dilator and providing a passageway for the introducer sheath into a body opening. Gill et al. teach, at least in figures 8-10 and in col. 5 lines 49-51 and col. 6 lines 27-34; a sheath member (16) for a cannula and a dilator (12). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Gill et al., to include a sheath member in the system of Boyd in view of Panzer. Such a device would allow the opening of a body incision or cavity and the holding of the introducer sheath and dilator, while the system is guided into the patient's body.

Response to Amendment

8. Applicant's arguments with respect to claims 29-38, 40, and 46-53 have been considered but are moot in view of the new ground(s) of rejection. The indication of allowable subject matter in claims 31, 33, 38, 40, 48, and 49 in the Office action of January 24, 2008 is hereby withdrawn in view of the new grounds of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773
August 14, 2008